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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,227	05/11/2001	Cosimo Donno	15258052100	8611

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER

KONTOS, LINA R

ART UNIT	PAPER NUMBER
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3751

DATE MAILED: 09/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/854,227

Applicant(s)

DONNO ET AL.

Examiner

Lina R Kontos

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: sentence spanning pages 5-6 of the specification reading “The simultaneously ring-shaped 10 outer surface 22 is seated on a counter-simultaneously ring-shaped 10 outer surface 22 is seated on a counter-surface 25.” It has been interpreted to read as “The simultaneously ring-shaped 10 outer surface 22 is seated on a counter-surface 25,” for the purposes of this examination.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected as claim 1, recites the limitation "the head" in line 2. There is insufficient antecedent basis for this limitation in the claim. For the purposes of this examination, “the head” was interpreted as being the head of the bone screw.

Claims 7-9 each cite a bone plate, and as the applicant fails to specify if these are different bone plates than cited in claim 1, claims 7-9 are rejected as having a double inclusion. Applicant needs to clarify whether the bone plates mentioned in claims 7-9 are different than the bone plate previously mentioned in claim 1. For the purposes of this examination, the bone plates mentioned in claims 7-9 were interpreted as being different than the bone plate in claim 1.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1,2,8,10 rejected under 35 U.S.C. 103(a) as being unpatentable over Ganem in view of Luhr et al. Ganem describes a bone-fixing device for use on vertebral bodies (column 7, lines 2-3) comprising a bone plate, bone screws, and a locking device to secure the bone screws. The bone screw has a spherical head with a flattened top (Figure 3) and the plug that secures the screw has a cut out that receives the head of the bone screw (column 2, lines 21-22), wherein the plug terminates within the edge of the bone plate (right side, Figure 3). The outer region of the plug is threaded (column 4, line 24) and plug appears to be half the height of the bone plate in the regions of the bone screws (left side, Figure 3). Holes extend through the bone plate to receive the bone screws, wherein the lower portion of the holes have a spherical cup serving to cradle the bottom of the screw head, (column 4, lines 2-5) allowing the screw to be positioned at varying angles. (column 4, lines 8-10)

Luhr et al. teach a bone plate for use on the cranial or facial skeleton or for small fragments of other skeleton sections. The bone plate for use in the facial skeleton has a thickness between 0.4 and 0.7mm and the diameter of the hole receiving the bone screw is between 2 and 2.4mm. (column 2, lines 29-33) Luhr et al. describe the benefit of minimizing the thickness of the bone plate so that they do not cause visible elevations of the skin once they have been implanted. (column 2, 24-36) It would have been obvious to one of ordinary skill in the art at the

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time of the invention to vary the thickness of the bone plate depending on its application and to minimize the thickness of the plate per given situation as to decrease the invasiveness of the procedure and to ensure that the plates are not significantly visible in their implanted state.

4. Claims 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ganem in view of Luhr et al. in further view of Justis et al. Ganem and Lurh describe bone fixation devices as described above. Justis et al. describe a device used to stabilize the spine (column 1, lines 7-8) that has a spring-mechanism (column 2, lines 30-35) to allow for “accommodating the natural movement of the vertebrae relative to one another” (column 1, lines 58-62). It would have been obvious to one skilled in the art at the time of the invention to substitute a rigid plate spanning 2 vertebral bodies for a plate with flexibility to stabilize that region of the spine, while still allowing for some degree of natural movement.

Conclusion

5.

Claims 3-6 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US patents 6235033 and 6228085 are relevant to this application as they each describe a bone plate and bone screw connection utilizing securing screws.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lina R Kontos whose telephone number is (703) 306-4207. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory Huson can be reached on (703) 308-2580. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3588 for regular communications and (703) 305-3588 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0861.

LRK
September 10, 2002

 9-10-02

GREGORY HUSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700